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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,759	03/31/2004	Donald Lynn Bissett	8482D	7736

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EXAMINER	
ISSAC, ROY P	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,759	BISSETT ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of U.S. Application No. 10/097,716, now pending, which claims priority under 35 U.S.C § 119(e) from the provisional application 60/277,805 filed on 03/22/2001.

This Office Action is in response to Applicant's amendment/remarks/response filed 27 September 2006 wherein claims 5 and 16 has been cancelled, and claims 1-3, 6, 10 and 13 has been amended. No new claim is submitted. Claims 4, 7-9, 11-12, 14-15 and 17 depends from amended claims.

Currently, claims 1-4, 6-15 and 17 are pending in this application and under examination on the merits.

Rejections Withdrawn

The rejection under 35 U.S.C § 112, second paragraph with respect to the phrase "safe and effective" renders claim 1 indefinite is withdrawn, since said phrase is replaced with a specific range.

The rejection under 35 U.S.C § 112, second paragraph with respect to the term "retinoids" rendered claim 10 indefinite is withdrawn, since said term is replaced by specific compounds.

The rejection under 35 U.S.C § 112, second paragraph with respect to the term "derivative" rendered claims 5, 13 and 16 indefinite is withdrawn, since said term has been cancelled. The rejection is maintained for claim 11 since the phrase "palmitoyl derivative" is present in the amended claim.

Cancelled Claims

As indicated above, applicant's arguments/response filed 27 September 2006 cancelled claims 5 and 6. All rejections made with respect to the cancelled claims in the previous office action are withdrawn.

The following are new or modified rejections necessitated by Applicant's amendment filed 27 September 2006, wherein the limitations in all pending claims as amended now have been changed since the range of sugar amine is changed from "about 1% to about 5%" to "about 0.001% to about 4%", and the phrase "safe and effective amount" is changed to "from about 0.1% to about 50%" in claim 1. All pending claims depends from claim 1. The limitations in the amended claims have been changed and the breadth and scope of all claims have been changed. Therefore, all rejections from the previous Office Action, filed 03 July 2006, have been modified or withdrawn and are listed below.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, for **scope** of enablement because the specification, while being enabling for the treatment of

skin, treating the loss of skin elasticity, elastosis, sagging, or decreasing the tactile discontinuities of the skin, empolying the combination described herein, does not reasonably provide enablement for "regulating the condition of skin," in particular, decreasing the convolution of the dermal-epidermal border or decreasing the firmness of skin or increasing the tactile discontinuities of the skin.

The skilled artisan would view that the recitation, "**regulating** the condition of skin", would reasonably encompass both enhancing and reducing the tactile discontinuities of the skin, in both opposite directions, as well as the increasing and decreasing the firmness of skin. The term "regulate" is defined as "to reduce to order, method or uniformity." (Webster's Dictionary, Page 1913; PTO-892, Cited by the examiner). In order to accomplish the task of reducing to order, or brining a method to uniformity, the agent as claimed must be able to increase the tactile discontinuities of the skin as well as decreasing it.

The instant claims are drawn to the method for regulating the condition of skin. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to the method for regulating, i.e., encompassing both increasing and decreasing the tactile discontinuities of the skin.

The state of the prior art: The skilled artisan would view that regulating the tactile discontinuities in the skin, the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including increasing and decreasing the wrinkles in the skin, are highly unlikely.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that, regulating, encompassing both increasing and decreasing, the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject, is highly unpredictable since the skilled artisan would not understand how the same compound or agent could increase and decrease the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to use the

composition herein to regulate the many conditions of skin, or how to prevent, retard, arrest, or reverse the tactile discontinuities or wrinkles in the skin.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the ***Wands*** factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to achieve methods of regulating the condition of skin.

Response to Arguments

Applicant's arguments filed 27 August 2006 with respect to this rejection of claim 17 made under 35 U.S.C. 112, first paragraph of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention enabled as further discussed below.

As set forth in the office action dated, 07/03/06, the specification fails to enable one of skill in the art to "regulating the condition of skin." The skilled artisan would view that the recitation, "**regulating** the condition of skin", would reasonably encompass both enhancing and reducing the tactile discontinuities of the skin, in both opposite directions, increasing as well as decreasing the

firmness of skin. The applicant's response quotes the specification, ""regulating skin condition," included prophylactically regulating and/or therapeutically regulating skin condition, and **may** involve *one or more* of the following benefits (emphasis added)."' Note that such a description in terms of examples and general description of what is included without indicating what is excluded is not considered a clear definition. Applicant notes that, "Nowhere does the specification state that regulating the condition of skin includes *decreasing* the convolution of the thermal-epidermal border or *decreasing* the firmness of skin or *increasing* the tactile discontinuities of the skin, none of which would be considered a benefit." Applicant's admission regarding the lack of support in the specification for decreasing the convolution of the thermal-epidermal border or decreasing the firmness of skin or increasing the tactile discontinuities of the skin is noted. Since the specification admittedly lacks support for said conditions, "regulating the condition of skin" is deemed to have failed enablement.

Applicant's further admissions regarding the lack of support in the specification for "increasing the wrinkles in the skin" is noted. Since the composition is only useful in decreasing the wrinkles it is deemed incapable of "regulating skin condition."

As discussed above, the term "regulate" is defined as "to reduce to order, method or uniformity." (Webster's Dictionary, Page 1913; PTO-892, Cited by the examiner). In order to accomplish the task of reducing to order, or bringing a method to uniformity, the agent as claimed must be able to increase the tactile discontinuities of the skin as well as decreasing it.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "derivative" in these claims renders the claims indefinite. The recitation "derivative" is not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to the method of treatment encompassed by the recited phrase herein. One of ordinary skill in the art would clearly recognize that palmitoyl peptide derivatives would read on any of those compounds having any widely varying group that possibly substitute said compounds.

Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g., physical, chemical, physiological effects and functions. Thus, it is unclear and indefinite as to the "derivative" of compounds herein encompassed thereby.

Response to Arguments

Applicant's arguments filed 24 August 2006 with respect to this rejection of claims 11 made under 35 U.S.C. 112, second paragraph of record in the previous Office Action have been fully considered but they are not deemed

persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants assert that the term "palmitoyl peptide derivatives" is sufficiently defined as "palmitoyl" is readily understood by one of skill in the art to mean a C16 derivative. This argument is found unpersuasive. Applicants assert that derivative peptides are exemplified in the specification. Applicant further asserts that said term is not of widely varying group to render the term indefinite. This argument was found unpersuasive. As noted above, a description in terms of examples and general description of what is included without indicating what is excluded is not considered a clear definition. Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g., physical, chemical, physiological effects and functions. Thus, it is unclear and indefinite as to the "derivative" of the term "palmitoyl peptide" herein encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10, 12-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Murad et. al. (U.S.Patent No. 5,804,594; PTO-1449, Included bye the Applicant).

Murad et. al, discloses the use of glucosamine, and N-acetylglucosamine, both sugar amines, for the treatment of skin conditions. (Abstract and Example 3, Column 10, lines 22-67; Claim 3, Column 16, lines 34-43). Murad et. al further discloses the use of ascorbic acid Vitamin B_3 compound niacinamide (2.4%). (Example 3, Column 10, lines 22-67). Murad further discloses the use of 17.1% of N-Acetylglucosamine, 6.5% of D-glucosamine sulfate, Vitamin E succinate, and 15% of ascorbic acid. (Example 3, Column 10, lines 22-67). **Murat et. al. further discloses the use of 3 to 17% of glucosamine.** (Column 7, lines 30-35). Note that Vitamin E and its derivatives, as well as ascorbic acid are disclosed in the instant application as anti-oxidant/ radical scavengers. (Specification, Page 31, lines 4-22). Murad further discloses coconut oil in combination with said ingredients. (Example 3, Column 11, lines 1-5). Coconut oil is considered a dermatologically acceptable carrier. Murad further discloses topical administration of said combination for the treatment of skin wrinkles. (Column 8, lines 18-27).

The recitation "topical skin care" is considered the intended use of the claimed composition. Note that it is well settled that "intended use" of a composition or product, e.g., "topical skin care composition", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as

the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, claims 1-4, 6-10, 12-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Murad et. al.

Response to Arguments

Applicant's arguments filed 24 August 2006 with respect to this rejection of claims 1-4, 6-10, 12-15 and 17 made under 35 U.S.C 102(b) of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants have amended claims to preclude rejection under §102(b) over Murad et. al. However, as indicated in 102(b) rejection above, Murad et. al. discloses all the elements of the amended claims. The rejections are maintained because Murad et. al. covers the lower range. As such, the amended claims 1-3, 6-10 and 12-15 are anticipated by Murad et. al.

For the above stated reasons, said claims are properly rejected under 35 U.S.C 102(a). Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

> be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murad et. al. (U.S. Patent No. 5,804,594, PTO-1449, Included bye the Applicant), in view of Tanner et. al. (U.S. Patent No. 5,935,556, PTO-892, Cited by the examiner).

Murad et. al, discloses the use of glucosamine, and N-acetylglucosamine, both sugar amines, for the treatment of skin conditions. (Abstract and Example 3, Column 10, lines 22-67; Claim 3, Column 16, lines 34-43). Murad et. al further discloses the use of ascorbic acid Vitamin B_3 compound niacinamide (2.4%). (Example 3, Column 10, lines 22-67). Murad further discloses the use of 17.1% of N-Acetylglucosamine, 6.5% of D-glucosamine sulfate, Vitamin E succinate, and 15% of ascorbic acid. (Example 3, Column 10, lines 22-67). **Murat et. al. further discloses the use of 3 to 17% of glucosamine.** (Column 7, lines 30-35). Note that Vitamin E and its derivatives, as well as ascorbic acid are disclosed in the instant application as anti-oxidant/ radical scavengers. (Specification, Page 31, lines 4-22). Murad further discloses coconut oil in combination with said ingredients. (Example 3, Column 11, lines 1-5). Coconut oil is considered a dermatologically acceptable carrier. Murad further discloses topical administration of said combination for the treatment of skin wrinkles. (Column 8, lines 18-27).

Murad et. al. does not disclose the use of magnesium ascorbyl phosphate or one of the "skin care actives" listed in claim 11 for skin care compositions.

Tanner et. al. discloses the use of salicyclic acid, panthenol and derivatives and tocopherol and tocopherol acetate in skin care compositions. (Column 6, lines 61-Column 7, line 20). Tanner further discloses the use of magnesium ascorbyl phosphate, ascorbic acid, and nicacinamide in skin care compositions. (Column 7, lines 5-20). Tanner further discloses the use of sunscreen agents, structuring agents, and skin conditioners in the skin care composition. (Column 7, lines 30-60; Column 10, lines 34-17).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a skin care composition containing Vitamin B_3, a sugar amine, magnesium ascorbyl phosphate and salicyclic acid or panthenol or tocopherol.

Therefore one of ordinary skill in the art would have reasonably expected that combinations of vitamin B_3, sugar amines, tocopherol, panthenol and magnesium ascorbyl phosphate, all known useful for their use in skin care composition, would improve the therapeutic effects, and/or would produce additive therapeutic effects.

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicants' arguments filed 24 August 2006 with respect to this rejection of claim 11 made under 35 U.S.C 103(a) of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants assert that the office action failed to establish a prima facie case of obviousness because no motivation or suggestion to combine the references was given. Applicants' attention is directed to the office action dated, 07/03/06. (Page 10, Paragraphs 3 and 4). Combinations of vitamin B_3, sugar amines, tocopherol, panthenol and magnesium ascorbyl phosphate are all known for their use in skin care composition. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. Applicants further argue that Murad et. al. does not suggest a percentage of a sugar compound near the claimed range. Applicant's attention is drawn to the office action dated 07/03/06, page 9, noting that Murad discloses the use of 17.1% of N-Acetylglucosamine, and 6.5% of D-glucosamine sulfate. The 6.5% D-glucosamine sulfate is near the claimed range of about 0.001% to

about 4%. Furthermore, as noted above, Murat et. al. discloses the use of 3% to 17% of glucosamine. (Column 7, lines 30-35).

The applicant argues that there is no suggestion that the lower percentage of a sugar amine would be effective to impart a skin benefit when topically applied to skin. As noted in the office action dated 7/03/06, Page 8, the recitation "topical skin care" is considered the intended use of the claimed composition. Note that it is well settled that "intended use" of a composition or product, e.g., "topical skin care composition", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

The applicant argues that there is no indication that coconut oil, in particular in the disclosed amount, would satisfy the instant claim limitations. Specification defines, "The phrase "dermatologically-acceptable carrier", as used herein, means that the carrier is suitable for topical application to the keratinous tissue, has good aesthetic properties, is compatible with the actives of the present invention and any other components, and will not cause any untoward safety or toxicity concerns." One of ordinary skill in the art will view coconut oil to have said properties and to be suitable for topical application. As such, claim 11 is prima facie obvious over the combined teachings of the prior art.

Rejection under 35 U.S.C. 103(a) of claims 11 as being unpatentable over Murad et. al. (U.S. Patent No. 5,804,594, PTO-1449, Included bye the Applicant),

in view of Tanner et. al. (U.S. Patent No. 5,935,556, PTO-892, Cited by the examiner) Is still deemed proper and is adhered to.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/14/06

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